

PATENT
Attorney Docket No. 04914.0053-00000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Commissioner for Patents
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Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Applicant requests a pre-appeal brief review of this application. Claims 29-65 remain pending. Of these claims, claims 29 and 57-65 are independent. For the following reasons, Applicant requests withdrawal of the outstanding rejections.

35 U.S.C. § 103(a) Rejection Based on *Lindsay* in view of *Verkaart*

Claims 29, 30, 41-45, 48-50, 55, 58-62, 64, and 65 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Lindsay et al.* (U.S. Patent No. 4,433,971) in view of *Verkaart et al.* (U.S. Patent No. 5,707,431). For the following reasons, this rejection should be withdrawn as *Lindsay* and *Verkaart* fail to teach or suggest each and every element recited in independent claims 29, 58-62, 64, and 65.

In particular, independent claim 29, and similarly independent claims 58-62, 64, and 65, recites a fluid distribution module for causing and monitoring a circulation of fluids from and to a patient through an extracorporeal blood treatment device, comprising: "a degassing device

comprising: a first chamber having an inlet for a liquid; [and] a second chamber having a lid including a vent, a hydrophobic membrane closing an opening of the second chamber within the lid, and an outlet for discharging the liquid . . ." (emphases added).

Lindsay discloses a bubble trap for a cardioplegia system in which cardioplegia medication or a mixture of arterial blood and medication is delivered to the heart of a patient undergoing open heart surgery which includes a bubble trap in conjunction with the delivery system which separates air from the arterial flow and provides visual indication of an increase of air in the system, together with a flow means for lengthening the path of flow through the trap to achieve maximum separation of air from the arterial flow. (*Lindsay*, Abstract).

The Examiner admits that *Lindsay*, however, "does not specifically teach that the hydrophobic membrane is disposed within the lid portion, such that it closes the opening at the upper portion of the second chamber." (*Final Office Action*, p. 3, ll. 16-18).

In order to cure the deficiencies of *Lindsay*, the Examiner relies on *Verkaart* and alleges "*Verkaart* teaches that the top portion of the system comprises a lid portion 18 comprising a vent 6 and a flexible hydrophobic membrane 16 that is disposed within the lid portion, such that it closes the upper opening of the second chamber. (*Final Office Action*, p. 3, line 22 - p. 4, line 3). Applicant respectfully disagrees.

Verkaart discloses that "[t]he top of the chamber 8 is covered with a hydrophobic membrane 16, which is mounted in a two-part cap 18. The two-part cap 18 covers the chamber and provides a one-way valve made of a flexible upper surface 20 having gas outlet 6 therein and a seat 22" (emphasis added). (*Verkaart*, col. 2, ll. 55-59). *Verkaart* further discloses that "[t]he chamber [8] is divided into an outer portion 10 and an inner portion 12 by a generally cylindrical filter 14." (*Id.* at col. 2, ll. 31-33). Assuming that the outer and inner portions 10 and 12 of the chamber 8 of *Verkaart* are analogous to the claimed "first chamber" and "second chamber," respectively, the hydrophobic membrane 16, which the Examiner equates to the claimed "hydrophobic membrane," does not close an opening of the outer portion 10, or for that

matter, an opening of the inner portion 12, *within* the two-part cap 18, which the Examiner equates to the claimed “lid.”

First, Applicant notes that *Verkaart* distinguishes between the terms “covered” and “closed.” For example, *Verkaart* discloses that “[t]he top of the chamber 8 is covered with a hydrophobic membrane 16.” (*Verkaart*, col. 2, ll. 55-56). Conversely, *Verkaart* discloses that “the filter is closed by a top 34” (emphasis added). (*Id.* at col. 3, line 45). Accordingly, the fact that the hydrophobic membrane 16 covers the chamber 8, which is divided into the outer and inner portions 10 and 12, respectively, does not mean that the outer portion 10 or the inner portion 12 is necessarily closed by the hydrophobic membrane 16. Second, independent claim 29, and similarly independent claims 58-62, 64, and 65, requires that the hydrophobic membrane close an opening of the second chamber *within the lid*. As illustrated in FIG. 2 of *Verkaart*, the hydrophobic membrane 16 does not appear to *close* an *opening* of either the outer portion 10 or the inner portion 12 *in the cap 18*. Rather, the hydrophobic membrane 16 is supported by a structure 24 and sits above the upper ring 37 of the filter 14 in the cap 18. In the cap 18, there are no openings leading to the outer and inner portions 10 and 12, respectively, which are *closed* by the hydrophobic membrane 16.

Since *Verkaart* fails to overcome the above noted shortcomings of *Lindsay*, and no reason has been clearly articulated as to why the claims would have been obvious to one of ordinary skill in view of the prior art, a *prima facie* case of obviousness has not been established for independent claims 29, 58-62, 64, and 65. Accordingly, independent claims 29, 58-62, 64, and 65, and claims 30, 41-45, 48-50, and 55, which depend from independent claim 29, are patentable over *Lindsay* and *Verkaart*.

35 U.S.C. § 103(a) Rejection Based on *Lindsay* in view of *Verkaart*, and further in view of *Buckberg '469 or Buckberg '191*

Claims 31-33, 56, and 57 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Lindsay* in view of *Verkaart*, and further in view of *Buckberg '469*, and claims 51 and 63

stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Lindsay* in view of *Verkaart*, and further in view of *Buckberg* '191. For the following reasons, these rejections should be withdrawn as *Lindsay*, *Verkaart*, and *Buckberg* '469 fail to teach or suggest each and every element recited in independent claim 57, and *Lindsay*, *Verkaart*, and *Buckberg* '191 fail to teach or suggest each and every element recited in independent claim 63.

Specifically, independent claim 57, and similarly independent claim 63 recites, *inter alia*, “a second chamber having a lid including a vent, a hydrophobic membrane closing an opening of the second chamber within the lid, and an outlet for discharging the liquid” (emphases added). The deficiencies of *Lindsay* and *Verkaart* are discussed above.

With respect to *Buckberg* '469 the Examiner asserts that “Buckberg . . . teaches an extracorporeal cardioplegia delivery system for oxygenating blood comprising a withdrawal conduit (29, 40), a withdrawal pump 18, an oxygenator 20, a cardioplegia pump 24, and an infusion lumen . . . ” (*Final Office Action*, p. 6, line 21- p. 7, line 3). Further, with respect to *Buckberg* '191, the Examiner alleges that “Buckberg . . . teaches a cardioplegia treatment system comprising a degassing chamber for removing gas from blood. Blood passes into a first chamber, then rises into a second chamber . . . ” (*Id.* at p. 9, ll. 19-21). Such teachings, even if present in *Buckberg* '469 and *Buckberg* '191, however, do not teach or suggest, at least, “a second chamber having a lid including a vent, a hydrophobic membrane closing an opening of the second chamber within the lid, and an outlet for discharging the liquid,” as recited in independent claim 57, and similarly independent claim 63. Accordingly, since *Buckberg* '469 and *Buckberg* '191 fail to overcome the above noted shortcomings of *Lindsay* and *Verkaart*, and no reason has been clearly articulated as to why the claims would have been obvious to one of ordinary skill in view of the prior art, a *prima facie* case of obviousness has not been established for independent claims 57 and 63. Accordingly, independent claim 57 is patentable over *Lindsay*, *Verkaart*, and *Buckberg* '469, and independent claim 63 is patentable over *Lindsay*, *Verkaart*, and *Buckberg* '191. Moreover, claims 31-33, 51, and 56 are also allowable at least

due to their dependence from independent claim 29.

35 U.S.C. § 103(a) REJECTIONS OF DEPENDENT CLAIMS 34-40, 46, and 47

With respect to the rejection of claims 39 and 40 under 35 U.S.C. § 103(a) as being unpatentable over *Lindsay* in view of *Verkaart*, and further in view of *Strauss et al.* (U.S. Patent No. 5,837,905), the rejection of claims 46 and 47 under 35 U.S.C. § 103(a) as being unpatentable over *Lindsay* in view of *Verkaart*, and further in view of *Bringham et al.* (U.S. Patent No. 4,698,207), and the rejection of claims 34-38 under 35 U.S.C. § 103(a) as being unpatentable over *Lindsay* in view of *Verkaart*, and further in view of *Buckberg '469* and *Strauss*, claims 34-40, 46, and 47 are patentable over the cited references at least due to their dependence from allowable independent claim 29. *Strauss*, *Bringham*, and *Buckberg '469* fail to cure the deficiencies of *Lindsay* and *Verkaart* discussed above. Specifically, *Strauss*, *Bringham*, and *Buckberg '469* fail to teach or suggest, at least, "a second chamber having a lid including a vent, a hydrophobic membrane closing an opening of the second chamber within the lid, and an outlet for discharging the liquid," as recited in independent claim 29. Accordingly, claims 34-40, 46, and 47 are also patentable over the cited references.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

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